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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/814,151	03/21/2001	Gina Lynn Nick	01/700	2473

7590 04/09/2002

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EXAMINER
CHAUDHRY, MAHREEN F

ART UNIT	PAPER NUMBER
1627	2

DATE MAILED: 04/09/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/814,151	Applicant(s) NICK, GINA LYNN	
	Examiner Mahreen Chaudhry	Art Unit 1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-17 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-17 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claim 17 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The specification does not enable one having ordinary skill in the art to make an in vitro model mimicking the gastrointestinal tract. The specification merely recites five vessels containing "individual ingredients that serve to mimic the environment in a corresponding segment of the GI tract." It is considered that determining which "ingredients" mimic the segments of the GI tract in order to make an in vitro model of the GI tract would require undue experimentation for the following reasons:

a) The breadth of the claims. The claims recite "a first vessel containing ingredients that mimic the environment in a stomach segment," "a second vessel containing ingredients that mimic the environment in a small intestine segment," and "a third vessel containing ingredients that mimic the environment in a large intestine segment." The stomach, small intestine and large intestine each contain a vast range of components including enzymes, bacteria, bile salts, cell types, gastric juices and various secretions. The phrase "ingredients that mimic the

environment" would encompass innumerable components of the three different segments of the GI tract.

b) The nature of the invention. The invention is directed a process for measuring antioxidant activity in an in vitro model mimicking the gastrointestinal tract by introducing antioxidant sample into various vessels that "mimic the environment" of the stomach, small intestine and large intestine. Determining which of the innumerable components would be required to determine antioxidant activity in an in vitro model of the GI tract would clearly require undue experimentation.

c) The state of the prior art and the level of predictability in the art. One having ordinary skill in the art would be able to identify various components of the stomach, small intestine and large intestine. However, determining which of these numerous component would need to be included in vessels to mimic these segments of the gastrointestinal tract would not be apparent to one having ordinary skill in the art. For example, it would be unclear specifically which components of gastric juice would be required, which proteins and which enzymes would be required to mimic the gastrointestinal tract and determine antioxidant activity of a sample.

d) The amount of direction provided in the specification and the existence of working examples. The specification provides only limited direction in terms of the specific "ingredients" to be included in each of the vessels mimicking the various segments of the gastrointestinal tract. The specification does recite that the vessel mimicking the stomach should be maintained at an acidic pH and that the small intestine should include a "pancreatic fluid" and "bile salt solution." There is no direction as to what additional "ingredients" are required or even if these minimum requirements are sufficient to simulate the stomach and the small intestine.

Furthermore, there is no direction as to the "ingredients" required to simulate the large intestine. There is no working example of an in vitro model of the gastrointestinal tract.

e) The quantity of experimentation needed to make and use the invention. The quantity of experimentation required is considered to be high. A vast range of different components are present in the stomach, small intestine and large intestine and it would take extensive experimentation to determine which of these components would be required to adequately mimic the relevant segment of the gastrointestinal tract so as to permit a determination of the antioxidant activity of a sample.

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 1-17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1 and 4 are unclear with regard to "assaying the free radical scavenging effectiveness of the nutritional formulation." Previous to this recitation, the claims recite "detecting and measuring the relative population of said tagged oxygen radicals" and "calculating the free radical scavenging efficiency." These steps would appear to comprise an assay of "the free radical scavenging effectiveness of the nutritional formulation" therefore it is unclear what further limitation is encompassed by the phrase "assaying the free radical scavenging effectiveness of the nutritional formulation." Consider deletion of this phrase.

Claim 9 is unclear with regard to "a first sample of a nutritional formulation" and "a second sample of said nutritional sample." It is firstly unclear if the first and second samples of a nutritional formulation are the same or different. That the claim recites "a second sample of said nutritional sample," it would appear that these samples are the same. However, from dependent claims 11-16, it would appear that the first and second samples are different. Furthermore, the purpose of measuring the free radical scavenging activity of both the first and second samples and how these measurements relate to the overall measurement of the free radical scavenging efficiency of the nutritional formulation is unclear.

Regarding claim 11, the phrase "such as" renders the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

Claim 15 is unclear with regard to the phrase "an isolated form of vitamin E proven to have antioxidant activity." Since vitamin E is known to have antioxidant activity, it is unclear how the limitation "proven to have antioxidant activity" distinguishes the recited Vitamin E.

Claim 17 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite in that it fails to point out what is included or excluded by the claim language. This claim is an omnibus type claim. The claim recites "assaying solutions from said vessels using the optical antioxidant sampling process of the invention" and does not particularly point out the method steps by which the solution is assayed. An omnibus claims is indefinite in that it fails to point out what is included or excluded by the claim language.

Claim 17 recites the limitation "said gastrointestinal tract" in lines 4, 7, 13 and 16. There is insufficient antecedent basis for this limitation in the claim. The claim recites "an in-vitro

model mimicking the gastrointestinal tract" and does not specifically recite a gastrointestinal tract.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. Claims 1-3 and 9-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 5,939,395 issued to Yu et al. in view of U.S. Patent 4,573,761 issued to McLachlan. Yu et al. disclose a method of determining antioxidative efficacy of various samples including tocopherol (Column 5, Lines 30+). Yu et al. disclose that dichlorofluorescein-diacetate (DCFHDA) are added to an antioxidant sample and incubated (Column 5, Lines 31-36). Yu et al. further disclose that the fluorescence intensity of the sample is determined using a spectrofluorometer using an excitation wavelength at 488 nm and emission wavelength of 525 nm (Column 5, Lines 36-39). Yu et al. additionally disclose that antioxidative activity was calculated by comparison of the suppression rate of the antioxidant sample with a control (Column 5, Lines 45+). Yu et al. do not expressly disclose that the population of tagged oxygen radicals is determined using an optical fiber sensor. However, Yu et al. does teach that fluorescence intensity was measured using spectrofluorometry at excitation wavelength of 488 nm and emission wavelength of 525 nm. The specification of the instant application similarly describes that the optical fiber sensor transmits light at wavelength of 488 nm and has an

excitation wavelength of 525 nm (p 4). That optical fiber probes may be utilized to detect fluorescence from analytes is well-known in the art. McLachlan et al. teach a fiber optic probe for light scattering and luminescence measurements including fluorescence measurements (Column 4, Lines 45-50). It would therefore have been obvious to one having ordinary skill in the art to have determined antioxidative efficacy of any antioxidant sample according to the method taught by Yu et al. and to have measured fluorescence using known methods including optical fiber probes since such probes are known to be utilized for fluorescence measurements.

7. Claims 4-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yu et al. in view of McLachlan et al. and further in view of U.S. Patent 6,051,571 issued to Kelleher et al. The applicability of Yu et al. and McLachlan et al. to the instant invention has been discussed above. Yu et al. does not expressly disclose the addition of oxygen catalyst promoters to increase oxidative activity before measurement of oxygen radicals. However, Kelleher et al. teaches a method for measuring the antioxidative activity of a sample by the addition of radical generating systems including ferrous iron and tert-butyl hydroxide to the sample followed by measurement of dichlorofluorescein fluorescence (Column 28, Lines 54+). Kelleher et al. teaches that ferrous iron results in auto-oxidation in the produce free radicals in the form of hydroxyl radicals, superoxide anion radicals and hydrogen peroxide (Column 28, Lines 65+). Kelleher et al. Kelleher et al. further teach that test antioxidant samples were measured for their ability to prevent dichlorofluorescein oxidation in a free radical generating environment at an excitation wavelength of 485 nm and emission wavelength of 535 nm (Column 28, Lines 60+). It would therefore have been obvious to one having ordinary skill in the art at the time of the

invention to have utilized any oxygen catalyst promoter to generate a free radical environment as taught by Kelleher et al. in the method determining antioxidative efficacy as taught by Yu et al. since both Kelleher et al. and Yu et al. teach methods of determining antioxidative activity using dichlorofluorescein.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mahreen Chaudhry whose telephone number is (703) 605-1200. The examiner can normally be reached on Monday – Friday (8:30-5:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jyothsna Venkat, can be reached at (703) 308-2439. The official fax phone number for the organization where this application is proceeding or assigned is (703) 308-4556 or 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

mc
April 4, 2002

RALPH GITOMER
PRIMARY EXAMINER
GROUP 1200